FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland

AGENDA

The committee will discuss the potential cardiovascular risk associated with products in the class of peripherally-acting opioid receptor antagonists and the necessity, timing, design and size of cardiovascular outcomes trials to support approval of products in the class for the proposed indication of opioid-induced constipation in patients taking opioids for chronic pain.

Day 1: Wednesday, June 11, 2014

8:00 a.m.	Call to Order and Introduction of Committee	**Randall P. Flick, MD, MPH** Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	**Stephanie L. Begansky, PharmD** Designated Federal Officer, AADPAC
8:10 a.m.	Cardiovascular Assessment of Peripherally Active Mu-Opioid Antagonists	**Donna Griebel, MD** Director Division of Gastroenterology and Inborn Errors Products (DGIEP) Office of Drug Evaluation III (ODE III) Office of New Drugs (OND), CDER, FDA
8:35 a.m.	**GUEST SPEAKER PRESENTATION**	
	Role of Peripheral Mechanisms in Opioid Pharmacology	**Gavril Pasternack, MD, PhD** Anne Burnett Tandy Chair in Neurology and Laboratory Head, Molecular Pharmacology and Chemistry Memorial Sloan-Kettering Cancer Center
9:20 a.m.	Clarifying Questions	
9:50 a.m.	**BREAK**	
10:05 a.m.	**INDUSTRY PRESENTATION - COLLABORATIVE**	
10:45 a.m.	Clarifying Questions	
11:00 a.m.	**INDUSTRY PRESENTATIONS**	Cubist Pharmaceuticals, Inc.
	Alvimopan - Retrospective Evaluation of Opioid Withdrawal and Cardiovascular Safety With Long-term Use in Opioid-induced Constipation	**Jennifer Liscouski** Director, Regulatory Affairs Cubist Pharmaceuticals, Inc.

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AGENDA (cont.)

INDUSTRY PRESENTATIONS (CON'T)

		Kate Lane, PhD, DABT Director, Regulatory Nonclinical Cubist Pharmaceuticals, Inc. **Lee Techner, DPM** Vice President, Clinical Research Cubist Pharmaceuticals, Inc.
11:30 a.m.	Clarifying Questions	
11:45 a.m.	**LUNCH**	
12:45 p.m.	**INDUSTRY PRESENTATIONS**	Salix Pharmaceuticals, Inc.
	Introduction	**William P. Forbes, PharmD** Executive Vice President Medical, Research & Development and Chief Development Officer
	Clinical Pharmacology	**Pamela Golden, PhD** Associate Vice President Nonclinical and Clinical Pharmacology
	Clinical Review of Safety	**Craig Paterson, MD** Vice President Medical and Clinical Development
	Summary	**William P. Forbes, PharmD** Executive Vice President Medical, Research & Development and Chief Development Officer
1:30 p.m.	Clarifying Questions	

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AGENDA (cont.)

1:45 p.m.	**INDUSTRY PRESENTATIONS**	AstraZeneca
	MOVANTIK™ NDA	**William Mezzanotte, MD, MPH**
	Overview of MOVANTIK Efficacy and Safety in the Clinical Development Program	**Mark Sostek, MD**
	Cardiovascular Safety of MOVANTIK	**William B. White, MD**
2:30 p.m.	Clarifying Questions	
2:45 p.m.	**BREAK**	
3:00 p.m.	**INDUSTRY PRESENTATION**	Theravance, Inc.
	Preclinical Properties of Axelopran	**David Beattie, PhD** Pharmacology Theravance, Inc.
3:15 p.m.	Clarifying Questions	
3:25 p.m	**INDUSTRY PRESENTATIONS**	Develco Pharma Schweiz AG
	Introduction	**Dr. Nils Burger** Head Clinical Project Management Develco Pharma Schweiz AG
	Oral Naloxone Pharmacology and Pharmacokinetics	**Georg Petroianu, MD, PhD, FCP** Professor and Chair Cellular Biology and Pharmacology Associate Dean for Clinical Research Florida International University Herbert Wertheim College of Medicine
.	Oral Naloxone Clinical and Pharmacovigilance Overview	**Mori Krantz, MD** Cardiology Division, Denver Health Professor of Medicine University of Colorado Denver
3:40 p.m.	Clarifying Questions	
3:50 p.m.	**INDUSTRY PRESENTATION – COLLABORATIVE**	

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AGENDA (cont.)

4:00 p.m.	**FDA PRESENTATION**	
	End of Day 1 Summary	**Robert P. Fiorentino, MD, MPH** Medical Team Leader DGIEP, ODE III, OND, CDER, FDA
4:20 p.m.	Clarifying Questions	
4:30 p.m.	**ADJOURNMENT**	

Day 2: Thursday, June 12, 2014

8:00 a.m.	Call to Order and Introduction of Committee	**Randall P. Flick, MD, MPH** Chair, AADPAC
8:05 a.m.	Conflict of Interest Statement	**Stephanie L. Begansky, PharmD** Designated Federal Officer, AADPAC
8:10 a.m.	**INDUSTRY PRESENTATION - COLLABORATIVE**	
8:35 a.m.	**FDA PRESENTATIONS**	
	Post-marketing Risk Assessment Tools for Cardiovascular Safety Outcomes	**Sukhminder K. Sandhu, PhD, MPH, MS** Acting Team Leader Division of Epidemiology I Office of Surveillance and Epidemiology CDER, FDA
	Statistical Considerations in the Design of Randomized Controlled Cardiovascular Outcomes Trials	**Clara Y. Kim, PhD** Lead Mathematical Statistician Division of Biometrics 7 Office of Biostatistics CDER, FDA
9:05 a.m.	Open Public Hearing	
10:05 a.m.	Questions to Committee/Committee Discussion	
11:35 a.m.	**BREAK**	
11:45 a.m.	Questions to Committee/Committee Discussion (cont.)	
1:00 p.m.	**ADJOURNMENT**	